

## REMARKS

Claims 1-22 have been presented for examination. Of these claims, claims 1 and 8 have been amended to incorporate the limitation of claim 3, and claims 3, 21 and 22 have been cancelled. In addition, claim 1 has been amended to recite that the distillation apparatus includes a heater operated at a temperature in the range of 240° C to 270° C. Support for this amendment may be found in Example 6 of the application, which recites that distillation was performed in a distillation unit composed of a thin film evaporator connected to a rectification column (a type of fractionating column) and that the distillation conditions included a still heater temperature in the range of 240° C to 270° C. Accordingly, the amendments do not add new matter. Reconsideration of the application in view of the amendments and the following Remarks is respectfully requested.

### **35 U.S.C. §103(a) Rejection Based on Saebo et al.**

Claims 1-7 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Saebo et al. (U.S. 6,410,761). According to the Office Action, Saebo discloses a process for refining a conjugated linoleic acid-containing material using a distillation apparatus. The Office Action acknowledges that Saebo does not disclose a fractionating column in the distillation apparatus or multiple passes in the distillation step, but states that such features would be within the purview of one of ordinary skill in the art. Further, according to the Office Action, use of a fractionating column is “routine tweaking” that one skilled in the art would be motivated to use in order to improve purity. This position is respectfully traversed for the following reasons.

In 2003, at the time of the claimed priority date of the present application, it was believed that conjugated linoleic methyl esters (CLME) were too thermally unstable for distillation with a high temperature distillation apparatus such as a rectification column. See, 37 CFR 1.132 Affidavit of Joseph C. Rongione Ph.D. Under 37 CFR ¶1.132 at ¶5. A copy of this Affidavit is submitted herewith in support of this Response. This belief is demonstrated by Advances in Conjugated Linoleic Acid Research, Volume 2, Sebidio, J.L., Christie, W.E., Adolf, R., editors, AOCS Press, Champaign, IL 2003. In Chapter 5 of the reference, a copy of which is attached to the §1.132 Affidavit of Joseph C. Rongione as Exhibit A, is a discussion of various commercial syntheses of conjugated linoleic acids. Saebo, the author of Chapter 5, highlights the thermal instability of CLAs (page 73, Thermal [1,5] sigmatropic rearrangements of CLA isomers). Rongione Affidavit at ¶5. This reference states that the rearrangement of CLA to undesired isomers occurs at 220° C. The clear import from this reference, which was state-of-the-art at the time the present application was filed, is that temperatures of 220° C and above will result in undesirable rearrangement of the desirable CLA isomers. Id. at ¶5. The reference also states that molecular distillation, a low temperature distillation process, should be used for purification of the CLA.

The Chapter 5 reference is consistent with the disclosure in the Saebo patent cited in the Office Action. Saebo states, at col. 10, lines 25-35, that distillation of the CLA occurs at 190° C in a molecular distillation plant. According to Saebo, the advantage of using molecular distillation is the short time (less than 1 minute) at which the CLA is held at an elevated temperature. Saebo further states that conventional

batch distillation procedures that involve elevated temperatures of about 180-200° C for up to several hours are to be strictly avoided because of the formation of undesirable isomers. The emphasis on extremely short exposure time and avoidance of high temperature distillation methods in the Saebo reference teaches away from the use of a fractionating column having a heater (e.g., a still heater) operating at a temperature in the range of 240° C - 270 ° C, well above the temperature at which conjugated linoleic acid undergoes thermal rearrangement, as now recited in claim 1. See also, Rongione Affidavit at ¶¶6, 7. It is therefore submitted that, contrary to the Examiner's position, it would not have been obvious to utilize a fractionation column in the distillation of conjugated linoleic acid esters because the use of such a distillation method is contrary to the Saebo teaching that high temperature distillation methods are to be avoided due to the known thermal instability and rearrangement of conjugated linoleic acids at temperatures of 220° C. See also, Exhibit A, Chapter 5 at pp. 73-74. Given the Saebo teaching, one would have expected that use of a fractionating column, with its increased exposure time to elevated temperatures, would have resulted in an increase in undesirable isomers. Thus, one of skill in the art would not have had a reasonable expectation of success in employing a fractionating column to distill conjugated linoleic acids.

Applicants surprisingly discovered that, not only could a fractionating column be employed in a method for distilling conjugated linoleic acid esters, but that fractionation improved both the amount of conjugated linoleic acid in the resulting product stream, and the product yield. Rongione Affidavit at ¶¶ 7-10. This is evident from a comparison

of the results of Example 1 in the application with the results of Example 6. In Example 1, which uses a molecular distillation method similar to that suggested by Saebo, the distilled ester stream had a conjugated linoleic acid ester content of 80.34%. Rongione Affidavit at ¶¶8. By contrast, an ester stream similar to that used in Example 1 was distilled in Example 6 via distillation using a rectification (fractionating) column. The resulting distilled ester stream had a conjugated linoleic acid ester content of 83.03%, a significant improvement over the Example 1 method. Rongione Affidavit at ¶¶9-10. Further, the product yield for the ester stream recovered in Example 6 improved by 43% over the product yield resulting from Example 1, a significant increase. Rongione Affidavit at ¶¶9-10. Such results are completely unexpected in view of Saebo's clear teaching that high temperature, longer residence time distillation methods are to be strictly avoided. See, Rongione Affidavit at ¶10. Accordingly, it is submitted that the present claims 1, 2 and 4-7 are not obvious in view of the Saebo reference.

**35 U.S.C. §103(a) Rejection Based on Saebo in view of Baltes et al. and Sachtler**

Claims 8-20 have been rejected as being unpatentable over Saebo in view of Baltes et al. (U.S. 3,162,658), and further in view of Sachtler (U.S. 5,326,925). Baltes et al. merely discloses a process for the preparation of conjugated linoleic acids, and is completely silent with respect to a method of distilling conjugated linoleic acids. Thus, Baltes does not satisfy the deficiencies noted above with respect to the Saebo reference, and the proposed combination of Saebo and Baltes does not teach or suggest the use of a fractionating column to distill conjugated linoleic acid esters, as

now recited in claim 8. Nor would the use of such a fractionating column be obvious for the reasons recited above in connection with claims 1-7 and in the Rongione Affidavit.

Sachtler et al. is cited merely for allegedly disclosing a dual reaction system in an isomerization process. However, Sachtler does not relate to the preparation of conjugated linoleic acid esters and is completely silent with respect to a method for distilling a conjugated linoleic acid ester stream. Consequently, Sachtler does not satisfy the deficiencies noted in the proposed combination of Saebo with Baltes. Even if the references were combined as proposed, the combination does not teach or suggest the distillation method recited in amended claim 8, wherein the distillation of an ester stream containing conjugated linoleic acid esters is carried out in a distillation apparatus comprising a fractionating column.

For all of the above reasons, it is submitted that the claims, as amended, are patentable over the art of record, and reconsideration of the application and allowance of the claims are respectfully requested.

The Commissioner is authorized to charge any necessary fees or credit any overpayment to Deposit Account No. 13-0017 in the name of McAndrews, Held & Malloy, Ltd.

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Respectfully submitted,

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